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SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

a.	Submitter:	Vascular Control Systems, Inc. 32236-F Paseo Adelanto San Juan Capistrano, CA 92675 (949) 488-8700
b.	Contact Person:	Kathleen Roberts RA/QA Manager Telephone: (949) 488-8700 ext. 115 Fax: (949) 488-8708
c.	Date Summary Prepared:	July 8, 2005

2. Name of device, including trade name and classification name:

a.	Trade/Proprietary Name:	VCS Doppler Transceiver
b.	Classification name:	Flowmeter, Blood

3. Identification of the predicate device or legally marketed devices to which substantial equivalence is being claimed:

a.	Company:	Koven and Associates
	Device:	Mini Doppler II Ultrasound Flow Detector
	510(k):	K915550
	Date Cleared:	December 10, 1992
b.	Company:	Meadox Medicals, Inc.
	Device:	MS Disposable Rigid Doppler Probe
	510(k):	K930227
	Date Cleared:	September 16, 1993

4. Description of the device:

The VCS Doppler Transceiver is a battery powered pulsed Doppler ultrasound system designed for the evaluation of blood flow in vessels. An 8 MHz Doppler device, which plugs into the transceiver unit, emits a pulsed ultrasonic signal. A varying audible signal is produced when the device is placed upon a vessel within which there is flow. The frequency (i.e., pitch) of the signal is proportional to the blood velocity within the vessel. Distinctive tonal patterns are produced which are indicative of the flow pattern in terms of velocity vs. time. The volume of the tone may be adjusted by the means of a control on the transceiver. Rechargeable batteries power the transceiver. An 8 MHz transmitter in the transceiver periodically drives the ultrasonic transmitting sensor located at the tip of the device. The ultrasonic waves generated by the sensor travel through the tissue just under the device tip in a fairly narrow beam. The waves are then reflected back towards the device whenever they encounter a boundary between tissues of different densities. During the intervals when the unit is not transmitting, the device passes any reflected signals that it receives to a receiving circuit. This circuit amplifies the re-turning echoes, compares their frequency to that of the transmitted signal and converts any frequency differences into an audible tone.

5. Intended use of the device:

The VCS Doppler Transceiver is designed for the evaluation of blood flow in uterine arteries.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

The VCS Doppler Transceiver has the same device characteristics of the predicate devices except the Meadox Medicals device is a 20MHz device.

7. Brief summary of nonclinical tests and results:

Electrical Safety testing was conducted to IEC 60601-1 and UL 60601.

8. Conclusion

The VCS Doppler Transceiver does not raise new issues of safety, effectiveness, or performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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TUV Rheinland of North America, Inc.
c/o Ms. Tamas Borsai
12 Commerce Road
Newton, CT 06470

Re: K052209
VCS Doppler Transceiver, Model 09-0023-01
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (Two)
Product Code: DPW
Dated: August 12, 2005
Received: August 15, 2005

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052209

Device Name: VCS Doppler Transceiver

Indications for Use: The VCS Doppler Transceiver is designed for the evaluation of blood flow in uterine arteries.

Prescription Use _X_ AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052209